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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,500	07/22/2003	Greet Vanderkimpen	021565-119	1677
21839	7590	06/14/2006	EXAMINER	
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			ZHENG, LI	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/623,500	<b>Applicant(s)</b> VANDERKIMPEN ET AL.	
	<b>Examiner</b> Li Zheng	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2242004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-8 and 18, amendment to the elected claims 1 and 3-4, as well as cancellation of claims 15-18 in the reply filed on 4/13/2006 are acknowledged. Applicants argue that it would not be a serious burden to examine the claims of groups I-IV together (response, Page 7, last paragraph). Group IV is directed to plant cells, plants and seeds comprising distinct nucleotide sequences from those of Group I. However, given the claim amendments, during the examination, it was determined that it would not be an undue burden to search and examine the invention of groups I, III and V together. Groups I, III and V are therefore rejoined. As a result, claims 1-14 are examined on merits. The examiner, however, maintains the restriction requirement for all other groups. Applicants are advised that since the restrictions between Groups I, III and V are withdrawn, if any claim(s) that include(s) the limitation of the examined claims is/are presented in a continuation or divisional application, the claim of the application may be subject to a provisional statutory and/or nonstatutory double patenting rejection over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 no longer apply. MPEP804.01.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

2. The specification is objected to because it fails to meet the sequence rule of 37 CFR 1.821. The brief description of Figures 1-4 must refer to the sequences in those figures by their sequence identifies. The Corrections are required. See MPEP § 608.01(b).

### ***Claim Objections***

3. Claim 8 is objected to because of the following informalities: The typographic errors in recitations, "ISPA1" and "ISPA2". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn towards a corn root preferential promoter fragment/region.

As written, claims 1-4 read on a nucleic acid sequence *per se* which is found in nature and thus, is unpatentable to applicant. The nucleic acid sequence, as claimed, has the same characteristics as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See

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*American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that claims 1-4 be amended by inserting the term --isolated-- before "corn root preferential promoter" in line 1, to identify a product that is not found in nature.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is rejected to because it recites the limitation of SEQ ID NO: 14 from the nucleotide at position 1281-1308. However, SEQ ID NO: 14 only consists of 500 bp.

Claim 13 recites the limitation "said plants" in lines 3 and 5. It is unclear that the recitations refer to a single plant or multiple plants.

In claim 13: the recitation, "providing", renders the claim indefinite. It is unclear what the recitation encompasses. The metes and bounds are not clear.

6. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A view of the full content of the specification indicates that a nucleotide sequence having at least 97% sequence identity to the nucleotide sequence of SEQ ID NO: 1 from the nucleotide at position 1-338 or SEQ ID NO: 2 from the nucleotide position 11-1196 is essential to the operation of the claimed invention.

A view of the language of claim 1 indicates that the claim is broadly drawn to a genus of sequence having at least 97% sequence identity to the nucleotide sequence of SEQ ID NO: 1 from the nucleotide at position 1-338 or SEQ ID NO: 2 from the nucleotide position 11-1196. However, the specification does not describes any other species in the claimed genus except for SEQ ID NO: 1 or SEQ ID NO: 2. Neither the specification nor the prior art teaches the conserved structures in SEQ ID NO: 1 or 2 that are essential for the root preferential promoter activity. The only structures correlated with the activity of root preferential promoter activity are bases 1-338 of SEQ ID NO: 1 and 11-1196 of SEQ ID NO: 2. Therefore, given the breadth of the claim and the lack of further guidance, a person skilled in the art would conclude that applicants are not in possession of the whole claimed genus.

7. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleotide sequence of SEQ ID NO: 1 from the nucleotide at position 1-338 and SEQ ID NO: 2 from the nucleotide position 11-1196 as root preferential promoters in corn, does not reasonably provide enablement for any sequence having at least 97% sequence identity to the nucleotide sequence of SEQ ID NO: 1 from the nucleotide at position 1-338 or SEQ ID NO: 2 from the nucleotide position 11-1196 as root preferential promoters in corn or the nucleotide sequence of SEQ ID NO: 1 from the nucleotide at position 1-338 and SEQ ID NO: 2 from the nucleotide position 11-1196 as root preferential promoters in any other plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The specification teaches that SEQ ID NO: 2 from the nucleotide position 11-1196 is able to function as root preferential promoters in corn. Since the nucleotide sequence of SEQ ID NO: 1 from the nucleotide at position 1-338 is only a part of SEQ ID NO: 2 and likely to function similarly as SEQ ID NO: 2 from the nucleotide position 11-1196 as well as methods to test plant promoter are well known in the art, the nucleotide sequence of SEQ ID NO: 1 from the nucleotide at position 1-338 as root preferential promoter in corn is deemed to be enabled.

However, It is well known in the art that, using a promoter isolated from one species of plant would produce unpredictable results when said promoter is used to specify expression of a gene in another species of plant. Oommenn et al (1994, *The*

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*Plant Cell* 6:1789-1803) teach that the alfalfa isoflavone reductase promoter exhibits a different expression pattern in tobacco as compared to the expression in alfalfa. In tobacco, the alfalfa isoflavone reductase promoter expressed in vegetative tissues and in reproductive organs whereas the same construct only expressed in the root meristem, cortex and nodules of alfalfa plants (abstract). Furthermore, Fiedler U. et al. (1993, *Plant Mol Biol.* 22(4):669-79) also teach that an RY consensus sequence, "CATGCATG", acts as a negative transcriptional regulatory element in the seed-specific promoter of the *Vicia faba* non-storage seed protein gene, and as a positive transcriptional regulatory element in seed-specific promoters obtained from other plant structural genes (page 677, the paragraph bridging columns 1 and 2). Therefore, to test whether the nucleotide sequence of SEQ ID NO: 1 from the nucleotide at position 1-338 and SEQ ID NO: 2 from the nucleotide position 11-1196 can function as root preferential promoter in any plant would require undue experimentation.

It is also well known in the art that the promoter element essential for its function could be very small (Kim et al. 1994, *Plant Molecular Biology* 24: 105-117, abstract). For example, the DNA that is at least 97% sequence identity to the nucleotide sequence of SEQ ID NO: 2 from the nucleotide position 11-1196 could have up to 36 unmatched bases that are scattered along said nucleotide sequence. Since neither the specification nor the prior art teaches all the motifs required for the root preferential promoter activity, it is not known which bases are indispensable for such promoter activity along the promoter region and which bases are not. Therefore, in the absence of further guidance, undue experimentation would be required by one skilled in the art to make



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and use the claimed invention with DNA that has at least 97% sequence identity to the nucleotide sequence of SEQ ID NO: 1 from the nucleotide at position 1-338 or SEQ ID NO: 2 from the nucleotide position 11-1196. See *Genentech Inc. v. Novo Nordisk, A/S* (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

### ***Conclusion***

Claims 1-14 are rejected.

Claim 8 is objected to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Ashwin D. Menta'.

**ASHWIN D. MENTA, PH.D.**  
**PRIMARY EXAMINER**